Biographical Sketch For:

William (Bill) H. Duffell, Jr., Ph.D. is presently responsible for Regulatory and Government Affairs for Gambro BCT (Blood Component Technologies) in Denver, Colorado. Dr. Duffell has 23 plus years of experience with both small Venture Capitol companies and large multi-billion dollar corporations in the pharmaceutical, medical device and biotech industries. His experience includes business development for new innovative medical products, research and development, clinical research, quality assurance, regulatory affairs, reimbursement for new technologies, product launch, field sales support and product liability. He has brought a variety of medical products to market in domestic, European and Asian countries. Prior to joining Gambro, he served as an Officer and Vice President for Cyberonics, Inc. where he was responsible for developing and launching a novel new implantable therapeutic product for treating several Central Nervous System (CNS) disorders. Dr. Duffell is an *entrepreneur* who has devoted his career to strategic global product and business development taking patented intellectual properties from the bench, through proof of concept, clinical and regulatory hurdles, and into commercial sales. Dr. Duffell has provided strategic and crisis leadership in the development and defense of a number of high profile medical products including breast implants, innovative biomaterials for the treatment of urological disorders and implantable cranial neurostimulators.

Dr. Duffell has twice been appointed by the Commissioner of the Food and Drug Administration to serve as Industry Representative on Advisory Panels and presently is a member of FDA's Hematology and Pathology Advisory Panel. Dr. Duffell is an active participant on several AdvaMed (the primary trade association for medical device manufacturers) task force groups and is a member in the Regulatory Affairs Professional Society (RAPS) and the Food and Drug Law Institute (FDLI). In October, 1998, Dr. Duffell was called upon by Congressmen Tom Bliley and John Dingell to testify at a full Committee hearing on the Implementation of the Food and Drug Administration Modernization Act (FDAMA) and its impact on the development and market introduction of medical products and reimbursement for new technology healthcare products. In 1999, he was again called upon by both the U.S. Congress and the U.S. Senate, to provide an Industry update and a progress report on the implementation of FDAMA and to address global business issues affecting the healthcare industry.

Dr. Duffell received his B.S. in Biology from Rutgers University and his doctorate in Business Administration / Behavioral Sciences from Clayton University.

William H. Duffell, Jr., Ph.D.

PROFESSIONAL EXPERIENCE

Regulatory & Government Affairs, Gambro BCT, Denver, CO. August 2003 to Present. Provide strategic international business support in the areas of product development, clinical research, regulatory product registration / approval, quality systems, operational compliance (with GMPs, GLP and GCPs) and product reimbursement.

Vice President, Regulatory & Market Development, VisionCare Ophthalmic Technologies, LTD, Saratoga, CA. November 2002 to June 2003. A Venture Capitol backed startup business with manufacturing and R&D based in Tel Aviv, Israel. Position reports to the CEO and is responsible for providing global leadership in the areas of: clinical research, regulatory affairs, compliance, quality assurance/quality control, reimbursement and product approval / registration.

Vice President, Regulatory & Technology Development, Gambro BCT, Denver, CO. July 2000 to June 2002. See above description for Regulatory and Government Affairs.

Vice President, Regulatory & Clinical Affairs, Cyberonics, Inc., Houston, TX. May 1995 to July 2000. This US publicly owned entrepreneurial medical device business focuses on implantable medical devices for the treatment of CNS disorders. Annual sales at time of departure ~80 Million. Position reported to CEO/President and provided direction & guidance directly to the company's Board of Directors. Primary responsibility included the leadership, staffing and organizational development of the following departments or business areas:

- ✓ New business and technology development
- ✓ Intellectual property and patents
- ✓ Quality assurance and control
- ✓ Sales field support
- ✓ Pilot manufacturing
- ✓ Worldwide regulatory affairs
- ✓ Worldwide clinical research
- ✓ Labeling and promotional materials
- ✓ Product reimbursement and coding
- ✓ Customer service and product complaints
- ✓ Legal affairs
- ✓ Company announcements and press releases

Additional responsibilities included quarterly progress reports and presentations to the Board of Directors and private and public investor groups aimed at creating shareholder value and assuring future sources of investment, the establishment and recruitment of a domestic sales force, and general sales and marketing support for new product introductions.

Director, Regulatory Affairs and Quality Assurance (Corporate) & Director of Quality Assurance (Divisional, ConvaTec), *Bristol-Myers Squibb (BMS) Company, New York, NY. April 1991 to May 1995. Held several divisional assignments in addition to a Corporate role -- Medical Engineering Corp., Edward Weck Co. and ConvaTec. During this time, primary responsibilities focused on* liability, reimbursement, product approval, off label use, product positioning and launch *for pharmaceutical and medical device products. Corporate*

responsibilities centered around product licensing and company acquisition and divestiture including SWOT type analysis of:

- ✓ Funding and resource allocations
- ✓ Time to market
- ✓ Regulatory hurdles and barriers to market entry
- ✓ Competing technologies, market dynamics and customer definition
- ✓ Coding and reimbursement
- ✓ Technical and regulatory talent assessment
- ✓ Strategic alliances across companies
- ✓ Product risks and liabilities
- ✓ Proof of concept work

Senior Manager, Regulatory Affairs and Clinical Research, Dornier Medical Systems, Inc., Atlanta, GA. April 1989 to April 1991. This leading healthcare company in the field of lithotripsy, laser and ultrasound technology is headquartered in Munich, Germany. Additional products include diagnostic, imaging and general use urological and gastroenterology devices, as well as some new chemical entity pharmaceuticals. Primary achievements included the establishment of a U.S. regulatory and clinical research department and a bio-statistics group. Other areas of responsibilities included compliance with Good Manufacturing Practices Regulations (GMPs) and Good Laboratory Practices regulations (GLPs), sales support, reporting of complaints, MDRs and adverse experiences to domestic and foreign regulatory agencies, and the review and approval of product labeling/promotional material.

PREVIOUS PROFESSIONAL EXPERIENCE (1982 to 1989)

Manager, Regulatory Affairs for a start up ophthalmic pharmaceutical and device division of Bausch and Lomb, Inc. Clearwater, FL. July 1988 to March 1989. Product line included licensed surgical instruments, therapeutic and diagnostic medical devices, generic and ethical pharmaceutical products. Areas of primary responsibility included departmental leadership in developing regulatory and clinical research strategies to pursue domestic and foreign market approval for medical devices and pharmaceuticals, monitoring clinical trials, project management for new products, preparing regulatory submissions for both U.S. and foreign governments, design and review of product labeling, writing and reviewing QA/QC product and testing specifications, coordinating regulatory agency facility inspections, managing product complaints, coordinating product recalls and assuring general regulatory compliance applicable to the healthcare industry.

Additional Previous Experience: Held positions of increasing responsibilities in clinical research, regulatory affairs, and quality assurance from June 1982 to May 1988 as Director, Regulatory Affairs & Clinical Research for Theragenics (*a venture capitol backed company*); Manager, Regulatory Affairs & Clinical Research for C.R. Bard; Senior Clinical Research Associate for Monsanto/G.D. Searle; and Clinical Research Assistant for Johnson & Johnson's Janssen Pharmaceutica.

KEY PROFESSIONAL ACCOMPLISHMENTS

Provided leadership and direction for the preparation and FDA approval of: 6 NDAs, 28 ANDAs, 24 INDs, 10 PMAs, >200 510(k)s, >38 IDEs and numerous NDA, ANDA, IND, PMA, and IDE Supplements. Many of these submissions necessitated presentations to FDA Advisory Panels for initial product approval and / or to address or resolve safety concerns for products already on the market.

Commercial launch of a truly innovative and unprecedented implantable medical device with a compounded annual growth rate of >175%. Other novel product introductions include the Boron Neutron Capture Therapy (BNCT) and ophthalmic drug delivery system.

Twice called upon by the U.S. Congress and once by the U.S. Senate to provide testimony regarding the regulatory impact of legislation involving product development and reimbursement for new technologies in the medical device industry.

Aided in the establishment of national healthcare coverage by CMS (formerly HCFA) & Blue Cross/Blue Shield simultaneously with obtaining marketing approval of the NCP® System, a new technology involving a Class III implanted medical device requiring an FDA Pre-Market Approval (PMA).

Succeeded in obtaining *the* quickest original PMAA approval on record with FDA's CDRH division for a permanent Class III therapeutic implant (NCP System) -- < 180 days total and 19 days post FDA Advisory Panel review.

Provided crisis leadership of regulatory and compliance related issues involving silicone gel filled breast implants and related products. Worked with FDA to prevent enforcement initiatives against the manufacturer and parent corporation.

Served as Industry Representative on two separate product approval Advisory Committees - Ear, Nose and Throat (1997 to 2001) and Hematology and Pathology (2004 to 2008).

Sourcing, attracting and retaining personnel to be highly productive leaders and managers. Many of these persons have been sought by and retained by other operating divisions or departments within the parent corporations.

Second round public financing for Cyberonics Corporation (CYBX) with "Green Shoe" sold at >4x the initial IPO price based upon consistently managing market expectations which allowed for the potential to over achieve.

AREAS OF PRODUCT DEVELOPMENT EXPERIENCE

- ✓ *Drugs*: Allergy, Immunology, Anesthesiology, Oncology
- ✓ *Devices*: Plastic and reconstructive surgery, Ophthalmic, Gynecology, Handheld surgical instrumentation and Minimally Invasive Surgical Instrumentation
- ✓ *Diagnostics*: Urology
- ✓ *Drugs / Devices Combinations*: Gastroenterology, Ophthalmology, Central Nervous System
- ✓ *Device & Biologics*: Hematology
- ✓ *Diagnostics Imagery*: Fluoroscopy and Ultrasound

EDUCATION

Doctor of Philosophy, Business Administration 1987, Clayton University, St. Louis, MO, non-traditional degree program. Major study: Behavioral Sciences, with additional graduate level study in clinical pharmacology.

Bachelor of Science, 1982, Rutgers University, New Brunswick, NJ. Major area of study: Biology and Chemistry, with additional study in clinical psychology.

SPECIAL SKILLS & INTEREST

- Experienced in European & Japanese business practices and etiquette
- Legal: Product liability defense
- Motivational public speaking and media trained
- Employee development and mentoring
- Behavioral analysis
- Biostatistics
- Negotiations
- Languages: Greek (minimal)

PERSONAL INFORMATION

Proprietary information has been deleted.

Date CV last revised: March 19, 2004